DOCKET NO: 263099US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
HARTMUT GRUND, ET AL.	: EXAMINER: JACOBSON, M.L.
SERIAL NO: 10/518,542	:
FILED: MAY 24, 2005	: GROUP ART UNIT: 4174
FOR: BIAXIAL STRETCH TUBULAR FILM FOR THE PACKAGING WITH OR WITHOUT BONES ARE PASTE-LIKE FOODSTUFFS AND USE THEREOF	:

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Now, comes Dr. Hartmut Grund who deposes and states that:

1. I am a named inventor on the above-identified application.

2. I am a graduate of Justus-Liebig-University, Giessen, Germany and received my chemistry degree in the year 1978.

3. I have been employed by Naturin GmbH & Co. KG since 1978, and I have been conducting research in the field of sausage casings, shrink bags and meat packaging for 21 years.

4. I am familiar with the prosecution of the above-identified application (i.e., U.S. Application No. 10/518,542) and I have read the Office Action of July 7, 2008. According to the Office Action it appears that the USPTO believes insufficient factual evidence has been presented to show that a long-felt and unsatisfied need for "bone-in" meat product packaging films existed in the food packaging art at the time the present application

was filed. A "bone-in" meat product is a cut of meat that is offered for sale with a bone in place. Counsel informs me that the USPTO is further of the opinion that there is insufficient evidence showing that one of ordinary skill in the art would not have expected a film having a polyolefin inner layer to be significantly superior with respect to penetration resistance (e.g., damaging energy as per the test for damaging energy defined in DIN 53373) in comparison to packaging films having a polyamide inner layer.

5. I have read and understood the Grund patent (U.S. Patent No. 5,612,104) cited by the USPTO as evidence that the tubular packaging film described in the present application is obvious.

6. As stated above, I have been conducting research in the field of sausage casings, shrink bags and meat packaging for 21 years. It is my opinion that those of ordinary skill in the art would readily recognize that a long-felt and unsatisfied need for bone-in meat product packaging films existed at the time the present application was filed. My opinion is supported by the combination of:

(i) The history of patents with respect to avoiding punctures of meat packaging caused by bones;
(ii) press release of the company Sealed Air Corporation dated April 30, 2003, which is documenting the continued quest for improving the Cryovac TBG bag (comparative example 2 of present application) in order to reduce leaker rates due to bone punctures; and
(iii) a publication in the National Provisioner of September 2004, which is reviewing bone-in packaging (see Appendix III).

(i) Regarding the history of patents, U.S. Patent 6,004,599 (disclosed in the above-identified application) is referring to U.S. Patent 2,891,870 published in 1959 and describing the task of avoiding the perforation of plastic bags by bones inside of the package. The numerous patents with respect to this task thereafter give evidence of the long-felt need for a solution for this task.

(ii) In the press release of the company Sealed Air Corporation from April 30, 2003 (see Appendix III) the author reports that the problem of bone punctures exists in the market and the existing packaging films are not completely satisfactory for bone-in meat products by stating that:

> "TBG Small Patch Ham bag reduces bone punctures by more than 73 percent in retail display when compared to standard casings. The Cryovac TBG Small Patch Ham bag includes a puncture resistant patch ..."

(iii) In the publication "Tough Enough!" by Richard Mitchell in the National Provisioner of September 2004 (see Appendix III) the author suggests that existing packaging films are not completely satisfactory for bone-in meat products by stating:

> "Yet, even with many manufacturers enhancing their bone-in packaging, some processors say additional improvements still are needed before the products meet all of their requirements."

The author lists the technology sources contributing to his article, not mentioning that he has considered the Naturin GmbH & Co. KG or the mother company Viscofan S.A., which is marketing products having the structure described in the above-identified application.

7. It is therefore my opinion based at least in part on the objective evidence mentioned above, e.g., information found in technical publications familiar to those of ordinary skill in the packaging art, that those of ordinary skill in the packaging art had a long-felt and unsatisfied need for packaging bone-in meat products.

8. It is further my opinion based upon my personal experiences in the field of sausage casings, shrink bags and meat packaging that there existed a long-felt and unsatisfied need for packaging films for bone-in meat products. My personal opinion is based upon my personal discussions with colleagues in the field of meat packaging at and around the time the present application was filed. My colleagues include individuals in both the technical and

marketing branches of the meat packaging industry. In these discussions, my colleagues acknowledged that conventional packaging films were not acceptable for packaging bone-in meat products. Additionally my colleagues communicated to me that a packaging film having superior penetration resistance would be desirable for the purpose of packaging bone-in meat products.

9. My opinion is also based upon my observations during my career in the packaging producing industry. Through personal observation at grocery stores and butcher shops. At the time the present application was filed I observed that bone-in meat products such as prime rib of beef had a tendency to rupture or penetrate conventional bone-in meat packaging materials. Penetration of a packaging film compromises the integrity of the packaging and makes the meat product unsuitable for sale.

10. It is further my opinion that contrary to the position taken by the USPTO, the skilled artisan would have no reason to expect a polyolefin film to inherently provide greater puncture resistance in comparison to a polyamide film in the tubular packaging film claimed in the present application. My opinion is based upon the general properties of polyamide and polyolefin films that are readily accessible to and known by those of skill in the art. Physical properties of different types of thermoplastic films are readily available from sources such as www.matweb.com (see Appendix II). The physical properties elongation at break and tensile strength at break give an idea of the stress-strain curve for the material by marking the point of rupture. The values for elongation at break and tensile strength of LDPE polyolefin film and Nylon 6 polyamide film in machine direction (MD) and transversal direction (TD), based on the matweb-database-documented commercial grades in those material groups, are given in Appendix I and II, respectively. This information was obtained from www.matweb.com. Using the information obtained from www.matweb.com, which I believe to be accurate, I

determined the linearly approximated stress-strain curves for average LDPE film and average Nylon 6 film.

Nylon 6:	Tensile strength at break	MD	191 MPa
		TD	122 MPa
	Elongation at break	MD	233 %
		TD	387 %
LDPE:	Tensile strength at break	MD	26.1 MPa
		TD	21 MPa
	Elongation at break	MD	310 %
		TD	583 %

The approximated stress-strain curves for these materials are provided in the attached chart (Appendix I).

11. Those of ordinary skill in the art recognize that the area underneath the stress-strain curve is a measure of the total amount of energy that is absorbed during the tensile test up to the point in which the material, e.g. LDPE or Nylon 6, breaks or fails, thus representing a "damaging energy". In absence of comparable values for the puncture resistance of bi-axially oriented films of different polymer types (Nylon 6, LDPE,...), the physical properties elongation at break and tensile strength at break give an idea of the stress-strain curve for the material by marking the point of rupture and thus allow to roughly compare a "damaging energy". As is readily evident from the chart and the provided average values for Nylon 6 film and LDPE film, the average Nylon 6 film has a more than 5 to 7 times higher tensile strength, while the average LDPE film has only a less than twice as high elongation at break. Calculating the triangular areas underneath the approximated stress-strain curve leads to "damaging energies" of 223 MPa (MD) and 236 MPa (TD) for average Nylon 6 film, 40 MPa (MD) and 61 MPa (TD) for average LDPE film.

12. From the data shown above, it is my opinion that those of ordinary skill in the art would not believe that an LDPE film inherently provides a higher damaging energy in comparison to a Nylon 6 (polyamide) film. To the contrary, it is my opinion that those of

ordinary skill in the art would be of the opinion based on the above data, that a packaging film having a polyamide as an outside layer would provide superior resistance to penetration (e.g., superior damaging energy) in comparison to an LDPE (polyolefin) film.

13. The validity of my above described opinion, that those of ordinary skill in the art would not believe that an LDPE film inherently provides a higher damaging energy in comparison to a Nylon 6 (polyamide) film, up to today is also supported by the publication "Bags and Pouches: The Quest for the Bullet proof Pouch" by Christina Elston in Pharmaceutical & Medical Packaging News, February 2006 (see Appendix III). In this publication the author states that polyamide is a tough material and quotes a couple of persons who confirm this. In particular, the author states:

- "One of the toughest materials currently used in pouches is Nylon."
- "'For people who want a very tough barrier pouch, we give them Nylon,' Ozcomert says." [John Ozcomert, technical director at Beacon Converters (Saddle Brook, NJ)]
- "While EVA/Surlyn had been the industry standard for toughness, nylons have replaced it because of their superior strength, says Murak." [Jeff Murak, director of sales and marketing at Oliver Products (Grand Rapids, MI)]
- "The material features multiple layers of nylon separated by softer energy-absorbing layers. 'An exterior layer of nylon offers excellent abrasion resistance, while the internal layers add strength and puncture resistance,' he explains. The arrangement of layers creates an I-beam effect similar to the strengthening effect of multiple wood layers in plywood, explains Haedt." [Edward Haedt, marketing director Perfecseal (Oshkosh, WI); Nota bene: this description is revealing a structure which has a polyamide inside layer (and outside layer)!]
- "'Any films that contain nylon will immediately enhance puncture resistance [...],' Czarnopys says." [Mary Czarnopys, converted-products marketing manager Perfecseal (Oshkosh, WI)].

14. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

15. Further deponent saith not.

Hartmut Grund

Dr. Hartmut Grund

1.10.2008

Date

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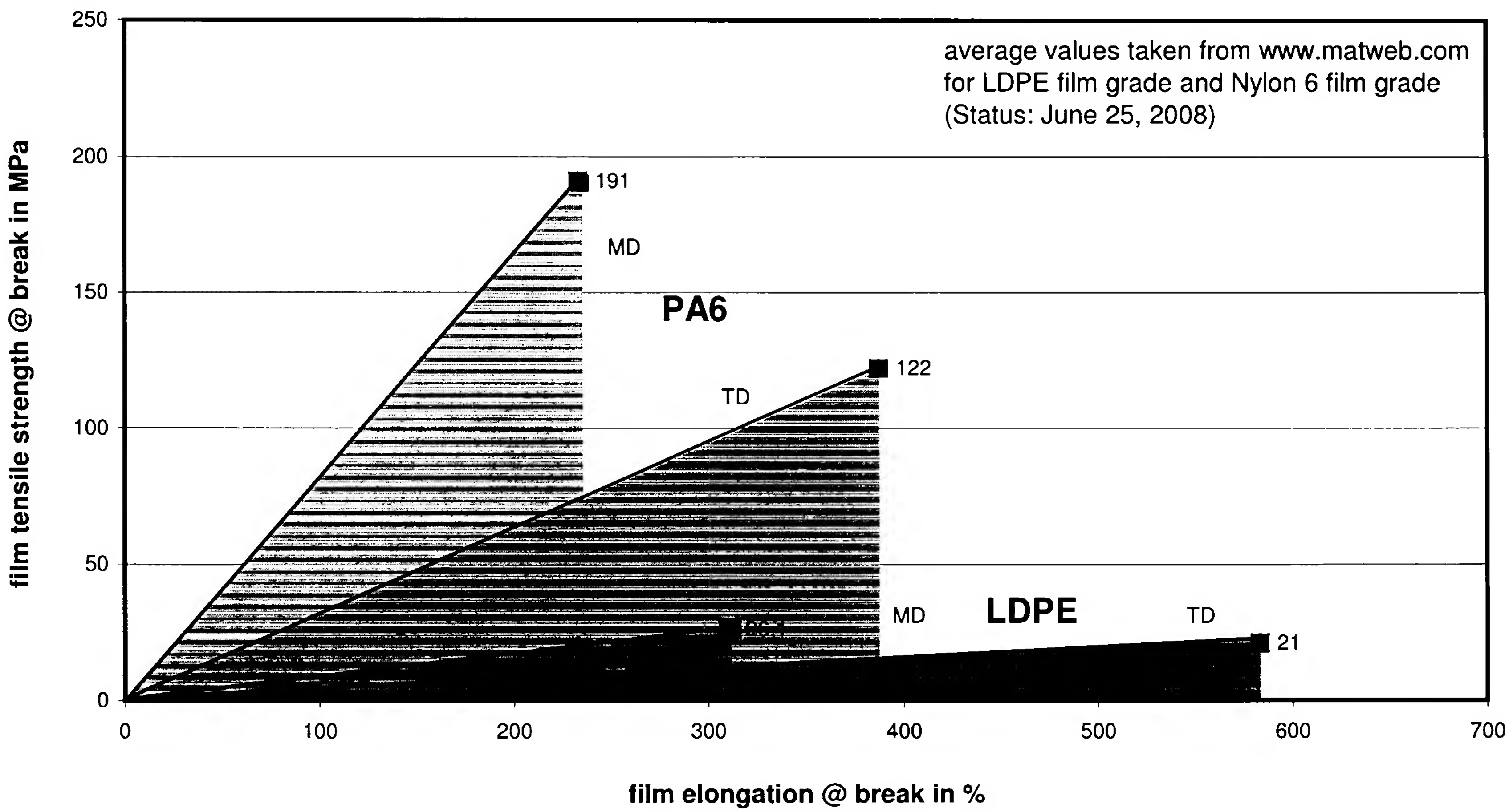
(OSMMN 05/06)

APPENDIX I

linear approximation of stress-strain-diagram of LDPE and PA6
(MD = machine direction, TD = transversal direction, energy uptake colored)



APPENDIX II

Overview of materials for Low Density Polyethylene (LDPE), Film Grade

Categories: Polymer; Thermoplastic; Polyethylene; LDPE; Low Density Polyethylene (LDPE), Film Grade

Material Notes: This property data is a summary of similar materials in the MatWeb database for the category "Low Density Polyethylene (LDPE), Film Grade". Each property range of values reported is minimum and maximum values of appropriate MatWeb entries. The comments report the average value, and number of data points used to calculate the average. The values are not necessarily typical of any specific grade, especially less common values and those that can be most affected by additives or processing methods.

Vendors: **Click here to view all available suppliers for this material.**

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Physical Properties	Metric	English	Comments
Density	0.917 - 0.932 g/cc	0.0331 - 0.0337 lb/	ade Count:245
Water Absorption	0.0100 %	0.0100	rade Count:30
Moisture Absorption at Equilibrium	0.0100 %	0.0100	rade Count:17
Environmental Stress Crack Resistance	168 hour	168 hc	Grade Count:4
Vinyl Acetate Content	1.50 - 6.60 %	1.50 - 6.60	ade Count:19
Thickness	12.7 - 150 microns	0.500 - 5.91 r	de Count:173
Melt Flow	0.180 - 60.0 g/10 min	0.180 - 60.0 g/10 m	10 min Grade Count:231
Antiblock Level	450 - 24000 ppm	450 - 24000 ppm	Average value: 2950 ppm Grade Count:26
Slip Level	250 - 1600 ppm	250 - 1600 ppm	Average value: 729 ppm Grade Count:17

II

Mechanical Properties	Metric	English	Comments
Hardness, Shore D	42.0 - 60.0	42.0 - 60.0	Average value: 50.6 Grade Count:32
Tensile Strength, Ultimate	7.85 - 34.5 MPa	1140 - 5000 psi	Average value: 13.1 MPa Grade Count:62
Film Tensile Strength at Yield, MD	6.89 - 28.0 MPa	1000 - 4060 psi	Average value: 11.1 MPa Grade Count:90
Film Tensile Strength at Yield, TD	6.21 - 15.2 MPa	900 - 2200 psi	Average value: 10.9 MPa Grade Count:94
Film Elongation at Break, MD	100 - 640 %	100 - 640 %	Average value: 310 % Grade Count:182
Film Elongation at Break, TD	249 - 1420 %	249 - 1420 %	Average value: 583 % Grade Count:181
Film Elongation at Yield, MD	5.40 - 330 %	5.40 - 330 %	Average value: 18.9 % Grade Count:26
Film Elongation at Yield, TD	5.00 - 520 %	5.00 - 520 %	Average value: 25.2 % Grade Count:26
Tensile Strength, Yield	8.30 - 15.0 MPa	1200 - 2180 psi	Average value: 11.4 MPa Grade Count:73
Elongation at Break	50.0 - 1000 %	50.0 - 1000 %	Average value: 417 % Grade Count:95
Elongation at Yield	13.0 - 100 %	13.0 - 100 %	Average value: 34.2 % Grade Count:23
Modulus of Elasticity	0.200 - 0.442 GPa	29.0 - 64.1 ksi	Average value: 0.271 GPa Grade Count:57
Flexural Modulus	0.214 - 0.262 GPa	31.0 - 38.0 ksi	Average value: 0.236 GPa Grade Count:5

Secant Modulus, MD	0.113 - 0.366 GPa	16.4 - 53.1 ksi	Average value: 0.193 GPa Grade Count:167
Secant Modulus, TD	0.00197 - 0.414 GPa	0.286 - 60.0 ksi	Average value: 0.220 GPa Grade Count:164
Impact	26.0 - 71.4	26.0 - 71.4	Average value: 43.6 Grade Count:11
Impact Test	0.300 - 31.2 J	0.221 - 23.0 ft-lb	Average value: 6.88 J Grade Count:8
Coefficient of Friction	0.0900 - 1.00	0.0900 - 1.00	Average value: 0.432 Grade Count:85
Tear Strength, Total	2.00 - 4.00 N	0.450 - 0.899 lb (f)	Average value: 3.00 N Grade Count:7
Elmendorf Tear Strength MD	85.0 - 1070 g	85.0 - 1070 g	Average value: 306 g Grade Count:112
Elmendorf Tear Strength TD	70.0 - 1370 g	70.0 - 1370 g	Average value: 238 g Grade Count:110
Elmendorf Tear Strength, MD	1.20 - 15.7 g/micron	30.5 - 400 g/mil	Average value: 8.44 g/micron Grade Count:82
Elmendorf Tear Strength, TD	2.10 - 22.2 g/micron	53.3 - 563 g/mil	Average value: 6.46 g/micron Grade Count:92
Dart Drop	1.40 - 49.2 g/micron	35.6 - 1250 g/mil	Average value: 3.76 g/micron Grade Count:138
Dart Drop Test	40.0 - 1500 g	0.0882 - 3.31 lb	Average value: 162 g Grade Count:133
Film Tensile Strength at Break, MD	14.0 - 72.0 MPa	2030 - 10400 psi	Average value: 26.1 MPa Grade Count:182
Film Tensile Strength at Break, TD	11.0 - 57.0 MPa	1600 - 8270 psi	Average value: 21.0 MPa Grade Count:178
Heat Seal Strength Initiation Temperarture	100 - 110 °C	212 - 230 °F	Average value: 105 °C Grade Count:11

Electrical Properties	Metric	English	Comments
Electrical Resistivity	1.00e+15 ohm-cm	1.00e+15 ohm-cm	Average value: 1.00e+15 ohm-cm Grade Count:30
Surface Resistance	1.00e+14 ohm	1.00e+14 ohm	Average value: 1.00e+14 ohm Grade Count:30
Dielectric Constant	2.30	2.30	Average value: 2.30 Grade Count:17
Dielectric Constant, Low Frequency	2.00 - 2.30	2.00 - 2.30	Average value: 2.17 Grade Count:30
Dissipation Factor	0.000200 - 0.000230	0.000200 - 0.000230	Average value: 0.000213 Grade Count:30
Dissipation Factor, Low Frequency	0.000200 - 0.000230	0.000200 - 0.000230	Average value: 0.000213 Grade Count:30
Comparative Tracking Index	600 V	600 V	Average value: 600 V Grade Count:30

Thermal Properties	Metric	English	Comments
CTE, linear 20°C	180 - 230 µm/m-°C	100 - 128 µin/in-°F	Average value: 198 µm/m-°C Grade Count:30
Melting Point	107 - 121 °C	225 - 250 °F	Average value: 113 °C Grade Count:89
Crystallization Temperature	95.0 - 104 °C	203 - 219 °F	Average value: 98.4 °C Grade Count:20
Deflection Temperature at 0.46 MPa (66 psi)	41.0 - 45.0 °C	106 - 113 °F	Average value: 42.9 °C Grade Count:17
Deflection Temperature at 1.8 MPa (264 psi)	41.0 - 45.0 °C	106 - 113 °F	Average value: 41.5 °C Grade Count:13
Vicat Softening Point	85.0 - 107 °C	185 - 225 °F	Average value: 94.6 °C Grade Count:133
Brittleness Temperature	-76.0 - -38.0 °C	-105 - -36.4 °F	Average value: -71.7 °C Grade Count:10
Flammability, UL94	HB	HB	Grade Count:30
Oxygen Index	17.0 - 18.0 %	17.0 - 18.0 %	Average value: 17.4 % Grade Count:30

Optical Properties	Metric	English	Comments
Haze	1.30 - 27.5 %	1.30 - 27.5 %	Average value: 8.02 % Grade Count:175
Gloss	8.20 - 120 %	8.20 - 120 %	Average value: 65.2 % Grade Count:172
Transmission, Visible	55.0 - 80.0 %	55.0 - 80.0 %	Average value: 78.2 % Grade Count:14

Processing Properties	Metric	English	Comments
Processing Temperature	143 - 260 °C	289 - 500 °F	Average value: 192 °C Grade Count:124
Blow-up Ratio (BUR)	1.50 - 3.00	1.50 - 3.00	Average value: 2.17 Grade Count:6

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Overview of materials for Nylon 6, Film Grade

Categories: Polymer; Thermoplastic; Nylon; Nylon 6; Nylon 6, Film Grade

Material Notes: This property data is a summary of similar materials in the MatWeb database for the category "Nylon 6, Film Grade". Each property range of values reported is minimum and maximum values of appropriate MatWeb entries. The comments report the average value, and number of data points used to calculate the average. The values are not necessarily typical of any specific grade, especially less common values and those that can be most affected by additives or processing methods.

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Physical Properties	Metric	English	Comments
Density	1.04 - 1.38 g/cc	0.0376 - 0.0500 lb/in³	Average value: 1.14 g/cc Grade Count:40
Water Absorption	1.60 - 9.50 %	1.60 - 9.50 %	Average value: 4.25 % Grade Count:4
Moisture Absorption at Equilibrium	2.70 - 3.00 %	2.70 - 3.00 %	Average value: 2.87 % Grade Count:7
Water Absorption at Saturation	9.00 - 9.50 %	9.00 - 9.50 %	Average value: 9.10 % Grade Count:5
Water Vapor Transmission	2.60 - 465 g/m²/day	0.167 - 29.9 g/100 in²/day	Average value: 149 g/m²/day Grade Count:17
Oxygen Transmission	4.00 - 40.3 cc-mm/m²-24hr-atm	10.2 - 102 cc-mil/100 in²-24hr-atm	Average value: 16.4 cc-mm/m²-24hr-atm Grade Count:3
Oxygen Transmission Rate	0.230 - 192 cc/m²/day	0.0148 - 12.4 cc/100 in²/day	Average value: 27.9 cc/m²/day Grade Count:24
Carbon Dioxide Transmission	72.8 - 220 cc-mm/m²-24hr-atm	185 - 559 cc-mil/100 in²-24hr-atm	Average value: 124 cc-mm/m²-24hr-atm Grade Count:5
Viscosity	3.15 - 85.0 cP	3.15 - 85.0 cP	Average value: 13.6 cP Grade Count:6
Thickness	10.2 - 59.0 microns	0.400 - 2.32 mil	Average value: 26.7 microns Grade Count:29
Melt Flow	22.8 - 34.5 g/10 min	22.8 - 34.5 g/10 min	Average value: 25.8 g/10 min Grade Count:4
Surface Tension	36.0 - 56.0 dynes/cm	36.0 - 56.0 dynes/cm	Average value: 52.9 dynes/cm Grade Count:17

Mechanical Properties	Metric	English	Comments
Tensile Strength, Ultimate	48.0 - 112 MPa	6960 - 16200 psi	Average value: 86.3 MPa Grade Count:6
Film Tensile Strength at Yield, MD	35.0 - 51.0 MPa	5080 - 7400 psi	Average value: 39.6 MPa Grade Count:10
Film Tensile Strength at Yield, TD	35.0 - 82.7 MPa	5080 - 12000 psi	Average value: 57.9 MPa Grade Count:14
Film Elongation at Break, MD	50.0 - 600 %	50.0 - 600 %	Average value: 233 % Grade Count:33
Film Elongation at Break, TD	55.0 - 900 %	55.0 - 900 %	Average value: 387 % Grade Count:25
Film Elongation at Yield, MD	10.0 %	10.0 %	Average value: 10.0 % Grade Count:4
Film	7.00 %	7.00 %	Average value: 7.00 % Grade

Elongation at Yield, TD			Count:4
Tensile Strength, Yield	28.0 - 90.0 MPa	4060 - 13100 psi	Average value: 63.8 MPa Grade Count:9
Elongation at Break	140 - 400 %	140 - 400 %	Average value: 332 % Grade Count:10
Modulus of Elasticity	1.10 GPa	160 ksi	Average value: 1.10 GPa Grade Count:4
Flexural Modulus	0.690 - 2.80 GPa	100 - 406 ksi	Average value: 2.04 GPa Grade Count:3
Flexural Yield Strength	39.0 - 120 MPa	5660 - 17400 psi	Average value: 86.3 MPa Grade Count:3
Secant Modulus	0.650 GPa	94.3 ksi	Average value: 0.650 GPa Grade Count:6
Secant Modulus, MD	0.285 - 4.69 GPa	41.3 - 680 ksi	Average value: 2.17 GPa Grade Count:22
Secant Modulus, TD	0.285 - 3.70 GPa	41.3 - 537 ksi	Average value: 2.17 GPa Grade Count:20
Coefficient of Friction	0.150 - 2.00	0.150 - 2.00	Average value: 0.516 Grade Count:27
Coefficient of Friction, Static	0.370 - 1.00	0.370 - 1.00	Average value: 0.595 Grade Count:4
Tear Strength Test	30.0 - 14000	30.0 - 14000	Average value: 1250 Grade Count:22
Tear Strength, Total	15.0 N	3.37 lb (f)	Average value: 15.0 N Grade Count:4
Tear Strength	50.0 kN/m	285 pli	Average value: 50.0 kN/m Grade Count:4
Elmendorf Tear Strength MD	56.0 g	56.0 g	Average value: 56.0 g Grade Count:6
Elmendorf Tear Strength, MD	0.394 - 4.20 g/micron	10.0 - 107 g/mil	Average value: 1.85 g/micron Grade Count:4
Elmendorf Tear Strength, TD	1.57 - 7.87 g/micron	40.0 - 200 g/mil	Average value: 4.74 g/micron Grade Count:4
Film Tensile Strength at Break, MD	32.0 - 379 MPa	4640 - 55000 psi	Average value: 191 MPa Grade Count:33
Film Tensile Strength at Break, TD	29.0 - 303 MPa	4210 - 44000 psi	Average value: 122 MPa Grade Count:25
Izod Impact, Notched	0.450 - 10.7 J/cm	0.843 - 20.0 ft-lb/in	Average value: 3.69 J/cm Grade Count:4

Thermal Properties	**Metric**	**English**	**Comments**
Melting Point	215 - 260 °C	419 - 500 °F	Average value: 222 °C Grade Count:18
Deflection Temperature at 0.46 MPa (66 psi)	51.0 - 161 °C	124 - 322 °F	Average value: 121 °C Grade Count:3
Deflection Temperature at 1.8 MPa (264 psi)	60.0 - 75.0 °C	140 - 167 °F	Average value: 65.7 °C Grade Count:3
Shrinkage	0.200 - 15.0 %	0.200 - 15.0 %	Average value: 4.15 % Grade Count:23

Optical Properties	Metric	English	Comments
Haze	1.70 - 10.0 %	1.70 - 10.0 %	Average value: 5.05 % Grade Count:23
Gloss	80.0 - 180 %	80.0 - 180 %	Average value: 128 % Grade Count:15

Processing Properties	Metric	English	Comments
Processing Temperature	15.0 - 295 °C	59.0 - 563 °F	Average value: 226 °C Grade Count:13
Feed Temperature	225 - 250 °C	437 - 482 °F	Average value: 239 °C Grade Count:4
Rear Barrel Temperature	220 - 255 °C	428 - 491 °F	Average value: 241 °C Grade Count:5
Middle Barrel Temperature	240 - 265 °C	464 - 509 °F	Average value: 254 °C Grade Count:5
Adapter Temperature	240 - 265 °C	464 - 509 °F	Average value: 255 °C Grade Count:4
Die Temperature	245 - 265 °C	473 - 509 °F	Average value: 258 °C Grade Count:4
Mold Temperature	245 - 265 °C	473 - 509 °F	Average value: 256 °C Grade Count:4
Drying Temperature	80.0 - 100 °C	176 - 212 °F	Average value: 90.0 °C Grade Count:4
Dry Time	4.00 - 12.0 hour	4.00 - 12.0 hour	Average value: 8.00 hour Grade Count:4
Dew Point	-30.0 °C	-22.0 °F	Average value: -30.0 °C Grade Count:4

O2405

APPENDIX III

Cryovac® TBG Small Patch Ham Bag Cures Package Failure

New Technology Reduces Bone Punctures by More Than 73 Percent

DUNCAN, S.C. (April 30, 2003) - Sealed Air, a worldwide leader in fresh food packaging, introduces the Cryovac® TBG Small Patch Ham bag, a boneguard bag specifically designed for hams. The new package, ideal for butt and shank portion smoked hams, as well as whole smoked hams, reduces bone punctures by more than 73 percent in retail display when compared to standard barrier bags.

The Cryovac® TBG Small Patch Ham bag includes a puncture resistant patch that protects a small area on one side of the bag and a curved end seal for a more contoured and tighter fit. The patch and shape of the package prevent bone punctures, enabling retail meat department personnel to focus their energy on merchandising product, instead of reworking packages or cleaning purge.

In an abuse resistance study comparing standard barrier bags and the Cryovac® TBG Small Patch Ham bag, more than 18,000 shank portion hams were examined to determine when - during packaging, storage, distribution or retail display - the package integrity is most compromised. It confirmed that nearly 70 percent of the total shank-bone punctures occur during retail display and are the primary cause of rework or package failure. Using the Small Patch Ham bag reduced bone punctures during the retail display by more than 73 percent.

The Cryovac® TBG Small Patch Ham bag eliminates the need for soaker pads which can become saturated and lose their protective attributes, often resulting in tears or punctures to the bag. For more information about the Cryovac® TBG Small Patch Ham bag, contact cryovac.mkt@sealedair.com. Also see our

www.cryovac.com/whatsnew/pressrelease/archives/prq203_6.html

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BAGS AND POUCHES

The Quest for the Bulletproof Pouch

The latest material combinations improve both the barrier and the strength of bags and pouches.

Christina Elston

Photograph of Ultimate Gamma Packaging Courtesy Alcan Packaging Medical Flexibles Americas.

Tough applications such as packaging large surgical kits and vacuum forming to encapsulate sharp orthopedic implants demand tough materials. And while flexible packaging isn't likely to find itself in the line of fire, many medical device manufacturers would like to find "bulletproof" materials—especially for pouches.

Defining Bulletproof

The first challenge, of course, comes in defining bulletproof. And this can depend on the application. "From what type of bullet do you need protection?" asks Leslie Love, vice president of sales and marketing at Tolas Healthcare Packaging (Feasterville, PA). "I think the reason people talk about 'bulletproof' is because the ramifications of failure are so great. It's really important that we communicate well to come up with the most cost-effective package possible."

Even defining bulletproof in terms of abrasion and puncture resistance is difficult. "Because there is no ASTM standard abrasion-resistance test," says Jeff Murak, director of sales and marketing at Oliver Products (Grand Rapids, MI), "the industry is left to evaluate film using puncture-resistance testing that doesn't do a good enough job of recreating real-world scenarios."

Puncture resistance presents its own complexities. "There are several different kinds of puncture—including blunt, sharp, and cutting. The solutions for dealing with the various types of puncture are different," explains Dhuanne Dodrill, president and COO of Rollprint Packaging (Addison, IL).

Nylon

One of the toughest materials currently used in pouches is nylon. It has been shown to be about four times stronger, gauge for gauge, than polyester, according to John Ozcomert, technical director at Beacon Converters (Saddle Brook, NJ). "For people who want a very tough barrier pouch, we give them nylon," Ozcomert says.

While EVA/Surlyn had been the industry standard for toughness, nylons have replaced it because of their superior strength, says Murak. "End-users can thus drop thickness for thinner, better-performing nylon and get a better yield per pound, saving them money," he says.

Multilayer films created by blending nylon with polyethylene and its derivatives are much stronger than monolayer polyethylene films, says Edward Haedt, marketing director at Perfecseal (Oshkosh, WI). "In many cases, a multilayer nylon/polyethylene film can be stronger at 60% of the thickness than a comparable monolayer polyethylene film, while the cost per unit area of film is lower for the nylon/polyethylene film," Haedt says.

Sometimes the film orientation can add an extra degree of toughness, such as in a Perfecseal product called Ice film, says Haedt. The material features multiple layers of nylon separated by softer energy-absorbing layers. "An exterior layer of nylon offers excellent abrasion resistance, while the internal layers add strength and puncture resistance," he explains. The arrangement of layers creates an I-beam effect similar to the strengthening effect of multiple wood layers in plywood, explains Haedt.

Perfecseal also markets a high-density polyethylene film with a nylon core and easy-peel sealant, and just began using it in pouch applications last year, says converted-products marketing manager Mary Czarnopys. The material often allows customers to downgauge. "Any films that contain nylon will immediately enhance puncture resistance, and in some cases, abrasion resistance," Czarnopys says. "Customers who previously had to purchase 4-mil material from other companies can now purchase 3-mil HP-EZ Peel from us."

Alcan Packaging Medical Flexibles Americas (Chicago, IL) also manufactures numerous nylon coextrusions, forming films, and nylon laminate materials that meet a variety of abuse-resistant applications, says senior research associate Brent Thompson. These, he says, offer resistance to puncture, impact, and tearing, and

Polymer Blends

While nylon continues to advance, polymer blends and resins have also come a long way, says Dodrill. "Some of the polymer blends provide a lot more strength than some of the common nylon constructions being used today," she says. "There are a lot of new technologies out there that give us more options than we had just a few years ago. By blending the right resins together, you can achieve some outstanding properties."

These materials can be designed to offer good abrasion resistance and to stand up better to e-beam or gamma radiation sterilization than nylon does, adds Dodrill. Rollprint's FlexForm and ClearForm lines, for instance, can be used to make bags and pouches, as well as in form-fill-seal applications, and they often cost less than nylon. "You can get the same performance out of the polymer materials as you can from multiple layers of nylon," Dodrill says. "And we often can offer a nice cost advantage over nylon."

Packaging Large Kits

For large surgical kits, abrasion is a special problem. "The biggest issue for hospitals is that they put these up on metal racks, and then nurses come by and grab them and the material abrades on the rack," says Mike Oberkirch, marketing and operations director for pouches and bags at Amcor Flexibles (Mundelein, IL). Header bags made of a tough material—especially one with an outer layer of nylon—stand up to this well, he says.

As a nylon alternative for the same applications, Alcan offers Ultimate Header Film (UHF), a multilayer coextruded film that costs less than nylon. The material, available for approximately a year, has been saving customers money by eliminating nylon from the structure. "We've provided something that's not a nylon film and provides four attributes for medical customers—exceptional puncture and impact resistance, a high degree of clarity, and ultimate tear resistance. Essentially, UHF provides many of the attributes of nylon, but at a lower cost," says Thompson. "We have completed many substitutions with this film, and it has performed very well for our customers." Metal trays and devices won't puncture the clear film, which is compatible with EtO, gamma, and e-beam sterilization.

Some customers, however, find header bags difficult to open, according to Oberkirch. "To me, header bags are tougher to get into," he explains. One alternative is to use a bag created from a film with linear tear properties, such as Amcor's Unitear bag. This offers improved access, but at a cost. "What you give up, when you do that, is some level of toughness," says Oberkirch. The bags are generally strong enough to do the job but certainly not as strong as nylon header bags.

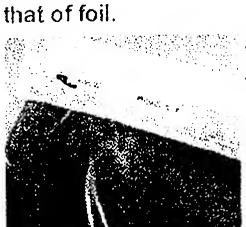
"Typically, if we get a complaint, it will often be because of abrasion," Oberkirch says. Device manufacturers, he explains, have to choose where they prefer to compromise. "A significant portion of the market," he says, "is moving to form-fill-seal for kits."

Vacuum Packing

Other challenging items to package are orthopedic implants—especially those that are vacuum packed. Perfecseal began making pouches from its Ice film in 2001 for just such an application, says Czarnopys, who adds that they've developed a significant customer base for the product. They're now working to develop a version with a longer shelf life, she says.

Unfortunately, says Oberkirch, it is difficult to find materials pliable enough to vacuum around the product, yet with the barrier properties to hold a vacuum during several years of shelf life. Many of the materials with these properties are subject to stress cracking, he says.

Films originally intended for form-fill-seal applications, however, can often be made into a bag or pouch pliable enough for the application. To add barrier properties, Ozcomert says that metallocene films, which stand up to vacuum forming without cracking, have now been developed to the point where their performance is close to that of foil.



The Ultimate Header Bag from Alcan Packaging Medical Flexibles Americas uses Ultimate Header Film, a multilayer coextruded film employed as an alternative to nylon.

Tolas supplies packaging for many orthopedic customers, says Love. For applications that do not require a moisture barrier, they might offer combinations of nylon plus linear low-density polyethylene, upgauging as needed to improve puncture resistance.

For applications that require a moisture barrier, "our primary foil-based laminate is a 48-gauge polyester with up to a mil of foil and a low-density polyethylene," says Love. To improve abrasion resistance, the outer polyester layer can be replaced with nylon. And if the customer wants to vacuum-pack the product, a softer, more flexible foil can be used. "There are more-formable foils that can be incorporated into these laminations," she says.

Tyvek Adds Toughness

In an effort to offer a new material that would fulfill customer needs for an absolute moisture and gas barrier, peelable seals, and superior puncture and abrasion resistance, Beacon Converters recently began using DuPont's Tyvek 2FS in a new way. Applying both a foil lamination and a peelable film to Tyvek 2FS, the company has created a material they call A34T, reports Ozcomert. Though the company has not yet formally begun marketing the product, they are working with DuPont to do shipping simulations that will "quantify some of the advantages of the material," Ozcomert says.

storage and provide a moisture barrier. "He needed something that would resist the cracking that takes place at liquid-nitrogen temperatures," Ozcomert says. Another used it provide puncture resistance in long, narrow pouches used for catheters.

"Foil has a tendency to pinhole and flex-crack," explains DuPont packaging consultant Karen Polkinghorne. She adds that the pairing with Tyvek would add strength, making the final material suitable for "any foil application that requires abrasion or puncture resistance," including packaging for drug-coated devices. "Some of the drug coatings are fairly sensitive to moisture or oxygen, and they need a high-barrier material," Polkinghorne says.

As new technologies such as drug coatings change devices, the ever-shifting definition of bulletproof will continue to change as well. "Can we make a bulletproof pouch for a specific application?" asks Dodrill. "Absolutely." But, she and others add, there is no single pouch that's bulletproof for everything. Packaging professionals instead must continue to match packaging to the specific needs of products, tackling each new application one challenge—or one bullet—at a time.

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September 2004

Tough Enough!

Tough Enough!

by Richard Mitchell

Bone-in packaging not only is strong enough to repel punctures, but attractive enough to appeal to retailers and consumers.

Case-ready meat and poultry's increasingly prevalent presence in retail aisles is having a catalyzing effect on packaging. In response to merchant demands for aesthetically appealing products that will grab the attention of consumers, packages are being designed with greater clarity and striking graphics. And with bone-in products becoming more popular, manufacturers are adding elements for greater strength and resiliency to withstand stresses from shipping and handling and to prevent punctures.

"Bone-in packaging on the store shelf has to be stronger and look much nicer than the typical packages of the past." says Mike Hiteshaw, global marketing manager of perishable food packaging for DuPont Packaging, a Wilmington, DE-based resin manufacture.

DuPont formulations include adhesives that are designed to bond together multiple layers of dissimilar films for enhanced functionality without diminishing clarity, he says. They include sealants that come in contact with the meat, and barriers that keep oxygen and moisture from entering and exiting bags. Nylons also are incorporated into outer layers for added durability

Recent enhancements are enabling the adhesives to seal faster and at lower temperatures, and allowing film clarity to be maintained after the sealing and shrinking procedures. Such processes are causing more processors to eschew the traditional patch bags in favor of packaging that contains stronger films throughout the design, Hiteshaw says.

"Retailers are demanding more merchandisable structures, so manufacturers can't necessarily produce packages with a big patch, an opaque patch, or a cloudy structure," he notes. "It has been a challenge because most of the materials that were good from a puncture resistant standpoint weren't necessarily clear."

Case-ready solution

Indeed, lucidity is becoming increasingly important as more packers — who once shipped large primals to butchers in vacuum bags for in-store cutting — now are producing a variety of cuts in bags that go directly to store displays, says Dave McCaffrey, vice president and general manager of Totowa, NJ-based Inovpack Vector Inc.

Inovpack Vector is supporting case-ready, bone-in meat and poultry with its Vector 80, and lighter weight Vector 30, patchless, high-barrier shrink bags that contain three layers of nylon-based film for added protection.

"Processors want bags that are strong but also have more eye appeal so they are putting greater value on clarity and products with attractive print," he notes.

Demand for sturdy bone-in packaging also is coming from foodservice operators, hotels, and consumers who want to reheat pre-cooked items without removing the food from its original bags. Such dishes can be prepared faster, often marinate better and are more tender when reheated, McCaffrey says.

He adds that potent cook-in bags that users can boil or roast bone-in meat and poultry in also are becoming more popular as processors and merchants take steps to minimize the handling of meat to reduce the threat of contamination.

To more effectively shield products, manufacturers also are designing packages to protect specific types of cuts. Oshkosh, WI-based Curwood Inc., for instance, is offering a variety of bone-in shrink bags as part of its ArmorX ABP line:

- **ABP 35** is intended for bone-in pork spareribs, St. Louis style spareribs; back ribs, bone-in loins, picnics, butts, and shanks.

- **ABP 55** is designed for smoked turkeys, bone-in hams, smoked picnics, and smoked butts.

- **ABP 65** is formulated for beef back ribs, short ribs, short loin, lamb rack, and lamb chops.

The bags contain high-oxygen and moisture barriers that are designed to maximize shelf life, and have high-shrink multilayer coextrusions laminated together for greater strength.

It is essential that case-ready, bone-in products have tight shrink to be visually appealing and help minimize the threat of juices seeping out of the beef, says Bill Goerich, Curwood senior marketing manager.

"Case-ready bags also need to be puncture resistant," he notes. "That is especially important for products that are shipped to merchant sites that don't have in-store butchers on staff, as those retailers are not prepared to repackage leakers."

Reducing damaged packages

Restoring damaged packages also can be expensive. Frank Kitchell, marketing manager, fresh meat, for Chicago-based Alcan Packaging, says it can cost between 50 cents and $1 to replace a bag in addition to the labor charge for repacking the product.

Alcan is marketing three bone-in products under its ClearShield branded film. The B-3200, which is intended to hold beef and lamb, and the B-3300, which is formulated for pork and larger cuts such as a full loin, are constructed with heavier materials to contain the larger bones common to wholesale shipments.

Alcan's B-3350 retail product has a tighter shrink to control the tenderizing solutions that are used for ham, spareribs, baby-back ribs, and other items. The B-3350 also is designed to hold dry meats.

Each bag has a different grade of sealant that is formulated to withstand the stresses from specific types of fat, Kitchell says. The packages contain a blend of puncture-resistant polymers and are intended to support disparate types of bones.

Alcan also is focusing on providing bone-in bags with added lucidity so consumers can get a more explicit view of meat and

poultry prior to selecting products.

Clearer bags also enable butchers to better assess the marbling and the overall condition of meats before opening packages. The merchants then can more easily return products to processors if they are dissatisfied with the coloring.

Such clarity also allows butchers to more accurately gauge the type of cut in each bag. By then refrigerating the unopened packages, they can insure that a wide variety of meats are kept in stock.

"Meat and poultry have a shelf life of about three days once a butcher cuts the bag open," Kitchell notes. "But products can last thirty to forty-five days when bags remained sealed and properly refrigerated."

The bone-in packaging being marketed by Alcan and other manufacturers is formulated with puncture-resistance materials across the total perimeter of the product. The designs exclude such traditional components as patches and bone wraps. By strengthening the entire package, packers can avoid the labor-intensive task of orientating the bone in each cut of meat to a patch, Kitchell adds.

Yet, patch bags are also being upgraded to more effectively support bone-in meats and poultry. Duncan, SC-based Cryovac/Sealed Air, for instance, a developer of patches and films, is tailoring its products to protect specific cuts.

A variety of designs are needed because bone locations vary from cut to cut, and the products retain different amounts of moisture, says Jim Mize, Cryovac/Sealed Air director of marketing, fresh red meat.

"Sealability capabilities can be critical, especially for bags that need to hold moisture-enhanced pork products," he notes. "The ability to withstand abuse is more of an issue for beef packaging because those cuts tend to be bigger and heavier. But in each instance, it is important not to over-engineer the bags. Attaching extra material can diminish the packages' clarity."

Better presentation

Cryovac/Sealed Air's TPG patch bag line includes Max Patch, which has tight shrink for better case-ready presentation, Mize says. The patches are clear so consumers can gage the status of meat, and also read the nutritional information, cooking instructions and other print that is situated beneath the patch. Covering the print shields the ink from the stresses that occur during shipping and handling.

Other TPG designs include the Rotated Patch, which is intended for picnics that requires bone guards on the sides; and the Wide Patch, which provides coverage across the entire product and is best suited for meat and poultry being transported to the butcher shop for cutting.

"Clarity is not as important for wholesale packaging so you tend not to worry if a product going into the back room has too much patch," he notes. "But the consumer is more attracted to retail case products that are as tight and snug as possible without much material overhang."

Mize adds that the bags are being engineered to make it simpler for processors to align bones with the patches, and that users having difficulty matching the elements are likely using the wrong type of bag for their particular cut of meat. He says he expects market interest in bone-in packaging to become stronger as the popularity of case-ready products increases.

"Retailers over the long term will want to make their meat and poultry products more visually appealing, so the demands on packaging will grow" he notes.

Yet, even with many manufacturers enhancing their bone-in packaging, some processors say additional improvements still are needed before the products meet all of their requirements.

"We see small steps being taken, but large steps are needed to effectively sell case-ready bone-in products in the vacuum-packed, bone-guard bags," says Joe Weber, vice president of fresh pork for Smithfield, VA-based Smithfield Packing Co., a unit of Smithfield Foods. "There still is room for refinement in the appearance, clarity, and general presentation of the bag. That remains one of the weakest links in case ready."

He notes, however, that recent packaging upgrades, such as tighter shrink, are effectively retarding bacteria growth and helping to expand the shelf life of products.

"The demand for bone-in products will not go away, and the packaging will continue to evolve," Mize adds. NP

Technology sources contributing to this article include:

- Alcan Packaging, phone (773) 399-8513, fax (773) 399-3330, e-mail [illegible]@alcan.com, or visit www.alcanpackaging.com

- Cryovac/Sealed Air Corp., phone (864) 433-2000, or (800) 845-3456, fax (864) 433-2134, e-mail: mkt@sealedair.com, or visit www.cryovac.com

- Curwood Inc., phone (920) 303-7300 or (800) 544-4672, fax (920) 303-7227, e-mail: curwood@bemis.com, or visit www.curwood.com

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